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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,745	03/08/2001	Roman Turovskiy	257/049	8509

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EXAMINER

ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,745

Applicant(s)

TUROVSKIY ET AL.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25, 48, 61, 77 and 86-98 is/are pending in the application.
- 4a) Of the above claim(s) 3, 5, 7, 11, 21, 24, 48, 77 and 86-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6, 8-10, 22, 23, 25 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/28/02 & 11/10/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated March 2, 2004. Claims 1,2, 4, 6, 8-10, 22, 23, 25 and 61 are under consideration. The examiner thanks applicants for resubmitting IDS articles. The signed 1449 forms are attached. The amendments to the drawings are acknowledged and accepted.

Response to Arguments

1. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendments to the claims have changed the scope; thus, a new rejection has been applied.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 4, 6, 8-10, 22-23, 25 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanganov et al. in US Patent No. 5,876,367 in view of Gilson et al. in WO 99/58068.

Regarding claim 1, Kanganov et al. disclose a method for open surgical endarterectomy via providing an elongate member (such as 44) having a proximal end, a distal end, and an expandable filter (42) at the distal end, as recited in column 7, lines

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5-25; inserting the distal end of the elongate member into the internal carotid artery downstream of a lesion, as stated in column 7, lines 10-15 and seen in figure 5; expanding the filter, as recited in column 7, lines 20-25; inserting the proximal end of a tubular member (10/14) into the common carotid artery upstream of the lesion, as seen in figure 5; and flowing blood from the common carotid artery through a lumen of the tubular member (10/14) into the internal carotid artery, as discussed throughout the specification.

Applicant has not recited performing the methods steps in any particular order, such as step a, b, c or first, second, third, etc. Therefore, since applicant has not claimed a distinct order that the steps be completed, Kanganov et al. perform the steps stated above and thus accomplish the function of protecting debris from escaping.

Further, Kanganov et al. do not explicitly recite advancing a tubular member having proximal and distal ends over the elongate member to place the distal end of the tubular member within the internal carotid artery. However, it would be obvious to one with ordinary skill in the art and within the scope of the invention to advancing the tubular member having proximal and distal ends over the elongate member to place the distal end of the tubular member within the internal carotid artery although not explicitly recited. Kanganov et al. recite, "After the shunt is purged, proximal opening 12 is secured by a clamp (not shown). Filter catheter 43 having elongate member 44, filter mesh 42 is enlarged to cover substantially all of the cross-sectional area of the internal carotid artery lumen. Proximal opening 12 of shunt 10 is then inserted into common carotid artery 65 through an incision." Thus, which is inserted first would be obvious if

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not inherent to one with ordinary skill in the art to prevent debris from escaping. Further applicant has not demonstrated the criticality or advantage to the particular order of steps.

Moreover, Kanganov et al. do not explicitly recite contracting the filter by advancing a sheath distally. However, Kanganov et al. do recite a deployment sheath (51) where the filter (42) is contracted and removed through the sheath 51, as recited in column 6. Further, Gilson et al. teach a filter with a support frame (111) and moving a sleeve (105) distally to contract a filter (105), as recited on page 11. Thus, it would be obvious to one with ordinary skill in the art to modify the system of Kanganov et al. to include a filter with a support frame and to move the sheath (51) distally in order to contract the sheath since the function of contracting the filter is achieved.

Regarding claim 2, Kanganov et al. obviously disclose that as applied to claim 1 as well as an elongate member that is a wire, as recited in column 2, lines 33-37.

Regarding claim 8, Kanganov et al. obviously disclose that as applied to claim 1 as well as the carotid artery and internal carotid artery that are occluded by clamping to occlude the common carotid artery upstream of the lesion and to occlude the internal carotid artery downstream of the lesion, as discussed in columns 4-8 and seen in figure 5.

Regarding claim 9, Kanganov et al. obviously disclose that as applied to claim 1 as well as back-bleeding the tubular member to purge air, as recited in column 7, lines 5-25.

Regarding claim 10, Kanganov et al. obviously disclose that as applied to claim 1 as well as making an arteriotomy to access the lesion, as discussed throughout the specification.

Regarding claim 22, Kanganov et al. obviously disclose that as applied to claim 1 as well as a tubular member that has a port (16) between the proximal and distal ends, and wherein the elongate member is passed through the port as the tubular member is advanced over the elongate member, as recited in column 7, lines 5-25 and seen in figure 5.

Regarding claim 23, Kanganov et al. obviously disclose that as applied to claim 22 as well as a port that includes a hemostatic valve (16), as recited in column 7, lines 5-25 and seen in figure 5.

Regarding claim 25, Kanganov et al. disclose a method for open surgical endarterectomy, via providing an elongate member (such as 44) having a proximal end, a distal end, and an expandable filter (42) at the distal end; inserting the distal end of the elongate member (such as 44) into the internal carotid artery downstream of a lesion, as recited in column 7, lines 5-25 and seen in figure 5; expanding the filter (42); inserting a proximal end of a tubular member (10/14) into the common carotid artery upstream of the lesion; and flowing blood from the common carotid artery through a

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lumen of the tubular member into the internal carotid artery, as discussed throughout the specification.

Applicant has not recited performing the methods steps in any particular order, such as step a, b, c or first, second, third, etc. Therefore, since applicant has not claimed a distinct order that the steps be completed, Kanganov et al. perform the steps stated above and thus accomplish the function of protecting debris from escaping.

Further, Kanganov et al. do not explicitly recite advancing a first tubular member having proximal and distal ends over the elongate member to place the distal end of the first tubular member within the internal carotid artery. However, it would be obvious to one with ordinary skill in the art and within the scope of the invention to advancing the tubular member having proximal and distal ends over the elongate member to place the distal end of the tubular member within the internal carotid artery although not explicitly recited. Kanganov et al. recite, "After the shunt is purged, proximal opening 12 is secured by a clamp (not shown). Filter catheter 43 having elongate member 44, filter mesh 42 is enlarged to cover substantially all of the cross-sectional area of the internal carotid artery lumen. Proximal opening 12 of shunt 10 is then inserted into common carotid artery 65 through an incision." Thus, which is inserted first would be obvious if not inherent to one with ordinary skill in the art to prevent debris from escaping. Further, applicant has not demonstrated the criticality or advantage to the particular order of steps.

Additionally, Kanganov et al. do not explicitly recite *joining* the distal end of the second tubular member (such as 14) to the proximal end of the first tubular member.

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On the other hand, it would have been obvious to one with ordinary skill in the art at the time the invention was made to make a tube separable, thus including the step of joining the tubes, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Moreover, Kanganov et al. do not explicitly recite contracting the filter by advancing a sheath distally. However, Kanganov et al. do recite a deployment sheath (51) where the filter (42) is contracted and removed through the sheath 51, as recited in column 6. Further, Gilson et al. teach a filter with a support frame (111) and moving a sleeve (105) distally to contract a filter (105), as recited on page 11. Thus, it would be obvious to one with ordinary skill in the art to modify the system of Kanganov et al. to include a filter with a support frame and to move the sheath (51) distally in order to contract the sheath since the function of contracting the filter is achieved.

Regarding claim 61, Kanganov et al. disclose a medical device for open surgical endarterectomy, having a first tubular member (14) having a proximal end, a distal end, and a lumen therebetween communicating with a distal port (13), a first proximal port (intersection of 14 and 10), and a second proximal port (at 16); a hemostatic valve (16) mounted in the second proximal port, as seen in figure 5; a second tubular member (10) having a proximal end, a distal end, and a lumen therebetween; and an elongate member (44) inserted through the hemostatic valve (16) and the second proximal port,

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the elongate member having a proximal end, a distal end, and an expandable filter (42) at the distal end.

However, Kanganov et al. do not explicitly recite a distal end of the second tubular member that is adapted for releasable attachment to the first proximal port of the first tubular member. On the other hand, it would have been obvious to one with ordinary skill in the art at the time the invention was made a distal end of the second tubular member that is adapted for releasable attachment to the first proximal port of the first tubular member, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Moreover, Kanganov et al. do not explicitly recite contracting the filter by advancing a sheath distally. However, Kanganov et al. do recite a deployment sheath (51) where the filter (42) is contracted and removed through the sheath 51, as recited in column 6. Further, Gilson et al. teach a filter with a support frame (111) and moving a sleeve (105) distally to contract a filter (105), as recited on page 11. Thus, it would be obvious to one with ordinary skill in the art to modify the system of Kanganov et al. to include a filter with a support frame and to move the sheath (51) distally in order to contract the sheath since the function of contracting the filter is achieved.

4. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanganov et al. in US Patent NO. 5,876,367 in view of Gilson et al. in WO 99/58068 and further in view of Hancock et al. in US Patent No. 6,610,077.

Regarding claim 4, Kanganov et al. as modified by Gilson et al. obviously disclose that as applied to claim 1. However, Kanganov et al. do not explicitly recite a filter that is slideably mounted on the elongate member. On the other hand, Hancock et al. teach a filter that is slideably mounted on the elongate member, as stated in column 9, lines 32-67. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Kanganov et al. to include a filter that is slideably mounted on the elongate member for the purpose of more flexibility.

Regarding claim 6, Kanganov et al. as modified by Gilson et al. obviously disclose that as applied to claim 1 as well as a filter with a plurality of flexible struts, each strut bonded to the elongate member at a proximal end, as stated in column 5. However, Kanganov et al. do not explicitly recite each strut having a distal end slideably mounted on the elongate member. On the other hand, Hancock et al. teach a filter that is slideably mounted on the elongate member, as stated in column 9, lines 32-67. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Kanganov et al. to include each strut having a distal end that is slideably mounted on the elongate member for the purpose of more flexibility.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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